<u>S/N 10/731,421</u> <u>PATENT</u>

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Mohan Krishnan et al. Examiner: Joseph Stoklosa

 Serial No.:
 10/731,421
 Group Art Unit: 3762

 Filed:
 December 9, 2003
 Docket: 279.650US1

Title: ENDOCARDIAL LEAD FOR A LEFT HEART CHAMBER

#### PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop AF Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

The applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a Notice of Appeal.

The review is requested for the reason(s) stated below:

#### § 103 Rejection of the Claims

Claims 1, 5, 7, and 9-18 are rejected under 35 U.S.C. § 103(a) as being obvious over Thoren (U.S. 4,149,542) in view of Helland et al. (U.S. 5,318,572; hereinafter "Helland").

#### Claims 1, 5, 7, 9, and 10

Applicant maintains the position in the response mailed September 8, 2009 that claims 1, 5, 7, and 9-18 are not obvious in view of the cited references since, even if combined, the combination does not include or suggest each limitation recited in the claim

Applicant believes there is a clear error of fact in the Examiner's position since each limitation recited in claim 1 is not found in the cited combination.

Claim 1 recites: A lead comprising:

a lead body extending from a proximal end to a distal end; and

a ring electrode coupled to the lead body;

wherein the lead body and the ring electrode each have an outer surface adapted to passively prevent formation of clots on the outer surfaces, wherein the outer surface of the lead body is adapted such that a layer of blood cells is formed on the outer surface when exposed to a bloodstream, and wherein the outer surface of the ring electrode includes a textured coating

including titanium microspheres.

However, Applicant cannot find in the cited combination: wherein the outer surface of the lead body is adapted such that a layer of blood cells is formed on the outer surface when exposed to a bloodstream, as recited in claim 1.

In contrast, Thoren discusses a lead with a side component 5 which is receptive to tissue ingrowth and Helland discusses a lead with the electrode tip having spheroidal particles 70 for chronic ingrowth of tissue. (Col. 6, lines 5-8). Neither reference discusses "a lead body adapted such that a layer of blood cells is formed on the outer surface when exposed to a bloodstream," as recited in claim 1.

In the Advisory Action dated September 21, 2009, the Examiner asserts that Helland discusses "microspheres allowing a layer of blood cells to form as blood passes through the pores created by the microspheres." (Page 2 of Advisory Action). However, the microspheres of the Helland reference are located on the electrode tip, they are not on the "lead body," as recited in claim 1. The Thoren reference does not overcome this deficiency. In the Thoren reference, the side component 5 is not the "lead body." Accordingly, claim 1 is not obvious in view of the cited references.

Claims 5, 7, 9, and 10 include each limitation of their parent claim and are also not obvious in view of the cited references. Reconsideration and allowance is respectfully requested.

#### Claims 11-16

Applicant believes claim 11 is not obvious in view of the cited references since the combination does not include or suggest each limitation recited in the claim. For instance, Applicant cannot find in the combination: wherein the lead body has a textured outer surface adapted to form a layer of blood cells on the outer surface when exposed to a bloodstream so as to passively prevent formation of clots on the outer surface, as recited in claim 11.

As discussed above, the references, both singly, and in combination do not include such subject matter.

Claims 12-16 include each limitation of their parent claim and are also not obvious in view of the cited references. Reconsideration and allowance is respectfully requested.

#### Claims 17 and 18

Applicant believes claim 17 is not obvious in view of the cited references since the combination does not include or suggest each limitation recited in the claim. For instance, Applicant cannot find in the combination: wherein means for passively preventing clots on the lead body includes forming the lead body such that a layer of blood cells is formed on an outer surface of the lead body when exposed to a bloodstream, as recited in claim 17.

As discussed above, the references, both singly, and in combination do not include such subject matter.

Claim 18 includes each limitation of its parent claim and is therefore also not obvious in view of the cited references. Reconsideration and allowance is respectfully requested.

Claims 1, 5, 7, and 9-18 are rejected under 35 U.S.C. § 103(a) as being obvious over Thoren in view of Helland and in view of Macgregor (U.S. 4,280,514).

### Claims 1, 5, 7, 9, and 10

Applicant traverses the obviousness rejection of claim 1. Applicant believes claim 1 is not obvious in view of the cited references since, even if combined, the combination does not include or suggest each limitation recited in the claim. For instance, Applicant cannot find in the cited combination: wherein the outer surface of the lead body is adapted such that a layer of blood cells is formed on the outer surface when exposed to a bloodstream, as recited in claim 1.

As discussed above, Thoren discusses a lead with a side component 5 which is receptive to tissue ingrowth and Helland discusses a lead with the electrode tip having spheroidal particles 70 for chronic ingrowth of tissue. (Col. 6, lines 5-8). The MacGregor reference does not discuss anything to do with a lead body. Accordingly, the combination does not include "a lead body adapted such that a layer of blood cells is formed on the outer surface when exposed to a bloodstream," as recited in claim 1.

Claims 5, 7, 9, and 10 include each limitation of their parent claim and are also not obvious in view of the cited references. Reconsideration and allowance is respectfully requested.

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Serial Number: 10/731,421 Filing Date: December 9, 2003

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## <u>Claims 11-16</u>

Applicant believes claim 11 is not obvious in view of the cited references since the combination does not include or suggest each limitation recited in the claim. For instance, Applicant cannot find in the combination: wherein the lead body has a textured outer surface adapted to form a layer of blood cells on the outer surface when exposed to a bloodstream so as to passively prevent formation of clots on the outer surface, as recited in claim 11.

Page 4

Dkt: 279.650US1

As discussed above, the references, both singly, and in combination do not include such subject matter.

Claims 12-16 include each limitation of their parent claim and are also not obvious in view of the cited references. Reconsideration and allowance is respectfully requested.

#### *Claims 17 and 18*

Applicant believes claim 17 is not obvious in view of the cited references since the combination does not include or suggest each limitation recited in the claim. For instance, Applicant cannot find in the combination: wherein means for passively preventing clots on the lead body includes forming the lead body such that a layer of blood cells is formed on an outer surface of the lead body when exposed to a bloodstream, as recited in claim 17.

As discussed above, the references, both singly, and in combination do not include such subject matter.

Claim 18 includes each limitation of its parent claim and is therefore also not obvious in view of the cited references. Reconsideration and allowance is respectfully requested.

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# **CONCLUSION**

The applicant respectfully submits that all of the pending claims are in condition for allowance, and such action is earnestly solicited. The Examiner is invited to telephone the below-signed attorney at (612) 359-3267 to discuss any questions which may remain with respect to the present application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

SCHWEGMAN, LUNDBERG & WOESSNER, P.A.

Page 5

Dkt: 279.650US1

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Date October 8, 2009

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<u>CERTIFICATE UNDER 37 CFR 1.8:</u> The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 8th day of 2009.

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